ARC 0374C

PHARMACY BOARD[657]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)*"b."*

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code sections 124.301 and 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 13, "Sterile Compounding Practices," and Chapter 20, "Pharmacy Compounding Practices," Iowa Administrative Code.

The amendments were approved at the August 29, 2012, regular meeting of the Board of Pharmacy.

The proposed amendments change definitions in Chapters 13 and 20 to clarify the terms used and to ensure uniformity of interpretation of like terms contained in both chapters. The proposed amendments also change the format of references to rules throughout by adding the Board's agency identification number to the references. Record requirements for sterile compounded drug products are added as new rule 657—13.8(155A), and the use of the same biological safety cabinet (BSC) or compounding aseptic isolator (CAI) for the compounding of nonhazardous sterile or nonsterile compounded drug products and for the compounding of hazardous drugs is prohibited unless the BSC or CAI is appropriately decontaminated between uses. The proposed amendments reorganize subrule 20.3(4) into paragraphs addressing specific sales and advertising issues and add a paragraph authorizing the compounding of drug products and placebos for dispensing to subjects in an approved university or college research project. The proposed amendments provide that a compounding production record is not required when personnel mix or reconstitute a drug according to the product's labeling or the manufacturer's directions and clarify that the record of an individual involved in any step of the compounding or verification process shall consist of the initials or other unique identification of that individual.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on October 23, 2012. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by e-mail to terry.witkowski@iowa.gov.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code sections 124.306, 124.308, 126.9, 126.10, 155A.2, 155A.4, 155A.13, 155A.13A, 155A.28, 155A.33, and 155A.35.

The following amendments are proposed.

ITEM 1. Amend rule 657—13.1(124,126,155A) as follows:

657—13.1(124,126,155A) Purpose and scope. These rules establish standards and procedures for the preparation, labeling, and distribution of sterile preparations by licensed pharmacies pursuant to a practitioner's order or prescription; for sterile product quality and characteristics; for personnel training, environmental quality, and equipment standards; and for pharmaceutical care. Sterile compounding differs from nonsterile compounding primarily by requiring the maintenance of sterility when preparations are compounded exclusively with sterile ingredients and components and by requiring the achievement of sterility when preparations are compounded with nonsterile ingredients and components. The standards and procedures outlined in this chapter apply to pharmacy practice when a preparation:

1. Is prepared according to the manufacturer's labeled instructions and requires other manipulations that expose the original contents to potential contamination;

2. Contains nonsterile ingredients or employs nonsterile components or devices that must be sterilized before administration; or

3. Is a biologic, diagnostic, drug, or nutrient that possesses characteristics of either "1" or "2" above and includes, but is not limited to, the following preparations that are required to be sterile when they are administered ~~to patients: baths and soaks for live organs and tissues,~~ into patient body cavities, central nervous and vascular systems, eyes, and joints, and when used as baths for live organs and tissues, such as injections (e.g., colloidal dispersions, emulsions, solutions, and suspensions), aqueous bronchial and nasal inhalations, irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.

Standards and safe practices for the compounding of radioactive preparations are identified in 657—Chapter 16.

ITEM 2. Amend rule **657—13.2(124,126,155A)**, definitions of "Compounding," "High-risk preparation," "Low-risk preparation" and "Medium-risk preparation," as follows:

"Compounding" means ~~the constitution, reconstitution, combination, dilution, or other process causing a change in the form, composition, or strength of any ingredient or of any other attribute of a product~~ preparing, mixing, assembling, packaging, and labeling a drug or device for an identified individual patient as a result of a practitioner's prescription drug order or initiative based on the prescriber/patient/pharmacist relationship in the course of professional practice or for the purpose of, or incident to, research, teaching, or chemical analysis, and not for sale or dispensing. All compounding, regardless of the type of product, is to be done pursuant to a prescription. Compounding also includes the preparation of drugs or devices in which all bulk drug substances and components are nonprescription or in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns pursuant to 657—subrule 20.3(3). Compounding does not include mixing or reconstituting a drug according to the product's labeling or to the manufacturer's directions.

"High-risk preparation" means a sterile preparation that is compounded from nonsterile ingredients; that is compounded with nonsterile components, containers, or equipment and requires terminal sterilization; or that meets the conditions of rule 657—13.13(155A).

"Low-risk preparation" means a sterile preparation that is compounded with sterile equipment, sterile ingredients, and sterile contact surfaces or that meets the conditions of rule 657—13.11(155A).

"Medium-risk preparation" means a sterile preparation that is compounded with sterile equipment, sterile ingredients, and sterile contact surfaces and involves complex or numerous manipulations of a sterile product or that meets the conditions of rule 657—13.12(155A).

ITEM 3. Adopt the following **new** definition of "Nasal inhalation" in rule **657—13.2(124,126,155A)**:

"Nasal inhalation" means a drug product or preparation, including the delivery device if applicable, whose intended site of deposition is the respiratory tract or the nasal or pharyngeal region. Nasal inhalation does not include a topical nasal spray or irrigation that is deposited primarily in the nasal passages.

ITEM 4. Amend subrule 13.6(1) as follows:

13.6(1) *Quality assurance program.* The policy and procedure manual shall include a quality assurance program pursuant to rule 657—13.31(155A).

ITEM 5. Amend subrule 13.6(2) as follows:

13.6(2) *Sampling.* The policy and procedure manual shall include procedures that require sampling of a preparation as provided in rule 657—13.29(126,155A) or if microbial contamination is suspected.

ITEM 6. Adopt the following **new** rule 657—13.8(155A):

657—13.8(155A) Record requirements.

13.8(1) *Production record.* A production record shall be prepared and kept for each drug product compounded for an individual patient. A production record is not required when mixing or reconstituting

a drug according to the product's labeling or the manufacturer's directions. The record shall include the following information:

a. Production date;

b. List of ingredients and quantity of each ingredient used;

c. Initials or unique identification of each person involved in each of the compounding steps;

d. Initials or unique identification of each pharmacist verifying each of the compounding steps;

e. Internal control or prescription number and, if the prescription is filled using a product compounded in bulk pursuant to rule 657—20.11(126), the internal control number assigned to the batch and recorded in the batch production record.

13.8(2) *Batch master formula record.* Pursuant to the provisions of 657—subrule 20.3(3), pharmacies may compound drugs in bulk quantities for subsequent prescription labeling and dispensing. For each drug product compounded in bulk quantity, a master formula record containing the following information shall be prepared:

a. Name of the product;

b. Specimen or copy of label;

c. List of ingredients and quantities;

d. Description of container used;

e. Compounding instructions, procedures and specifications.

13.8(3) *Batch production record.* For each batch of drug product compounded, a production record containing the following information shall be prepared and maintained:

a. The information from the master formula record;

b. Records of each step in the compounding process including:

(1) Preparation date;

(2) Identification of ingredients (including lot numbers);

(3) Quantities of ingredients used;

(4) Initials or unique identification of person completing each step;

(5) Initials or unique identification of pharmacist verifying each step;

c. Expiration/beyond-use date;

d. Internal control number;

e. Total yield.

ITEM 7. Amend rule 657—13.10(126,155A) as follows:

657—13.10(126,155A) Microbial contamination risk levels. Preparations shall be assigned an appropriate risk level—low, medium or high—according to the corresponding probability of contaminating a preparation with microbial contamination such as microbial organisms, spores, and endotoxins, and chemical and physical contamination such as foreign chemicals and physical matter. The characteristics described in rules 657—13.11(155A), 657—13.12(155A), and 657—13.13(155A) are intended as guides to the diligence required in compounding at each risk level.

ITEM 8. Amend rule 657—13.14(155A) as follows:

657—13.14(155A) Immediate-use preparations. The immediate-use provisions of this rule are intended only for those situations where there is a need for emergency or immediate administration of a sterile preparation. Such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the compounding of the preparation under low-risk level conditions would subject the patient to additional risk due to delays in therapy. Immediate-use preparations are not intended for storage for anticipated needs or for batch compounding. Medium-risk and high-risk preparations shall not be compounded as immediate-use preparations. Immediate-use preparations are exempt from the provisions of rule 657—13.11(155A) for low-risk preparations only when all of the following criteria are met:

1. to 6. No change.

ITEM 9. Amend subrule 13.20(3) as follows:

13.20(3) *Preparation area.* All hazardous drugs shall be compounded in a vertical flow Class II or Class III biological safety cabinet or in a compounding aseptic isolator containment and control device with biohazard control capabilities. A BSC or CAI used for the compounding of hazardous drugs shall not be used for the compounding of nonhazardous sterile or nonsterile compounded products unless the BSC or CAI is decontaminated in compliance with industry standards appropriate for inactivating hazardous drugs.

a. and *b.* No change.

ITEM 10. Amend subrule 13.20(8) as follows:

13.20(8) *Spills of hazardous drugs.* Written procedures for handling both major and minor spills of hazardous drugs shall be developed, maintained, implemented, and adhered to. The procedures shall be maintained with the policies and procedures required in rule 657—13.6(155A).

ITEM 11. Amend paragraph **13.31(2)"c"** as follows:

c. Reviewing documented patient or caregiver education and training required pursuant to rule 657—13.32(155A).

ITEM 12. Amend rule 657—20.3(124,126,155A) as follows:

657—20.3(124,126,155A) General requirements.

20.3(1) No change.

20.3(2) *Substances and components.* Pharmacists shall receive, store, and use bulk drug substances manufactured by an establishment that is registered with the FDA under the Federal Food, Drug, and Cosmetic Act and that, if requested, will provide a valid certificate of analysis for each drug product. Certificates of analysis shall be maintained pursuant to rule 657—20.12(124,126,155A). Bulk drug substances to be used in compounding drugs:

a. to *d.* No change.

20.3(3) *Prescriber/patient/pharmacist relationship.* A prescription for a compounded drug shall be authorized by the prescriber for a specific patient. Prescriptions for all products compounded at the pharmacy shall be maintained on file at the pharmacy as required by Iowa law. Pharmacists may compound drugs prior to receiving a valid prescription based on a history of receiving valid prescriptions generated solely within an established pharmacist/patient/prescriber relationship. Compounding based on a prescription history is bulk compounding and shall comply with the requirements of rule 657—20.11(126).

20.3(4) *Advertising and resale of compounded drug products.* The sale of compounded drug products to other pharmacies or to prescribers, except as provided in this subrule, is considered manufacturing.

a. Sale to practitioner for office use. ~~Pharmacists~~ A pharmacist shall not offer compounded drug products to other licensed persons or commercial entities for subsequent resale except in the course of professional practice for a practitioner to administer to an individual patient.

b. Sale to hospital pharmacy for administration to a specific patient. A pharmacy may sell to a hospital pharmacy a compounded drug product prepared pursuant to a prescriber's authorization for administration to a specific patient. The label affixed to the compounded drug product shall identify the pharmacy that compounded the product as the dispensing pharmacy. The original prescription drug order shall be maintained by the dispensing pharmacy. These rules shall not prohibit the hospital pharmacy from billing the patient or the patient's fiscal agent for a compounded product prepared for the patient and purchased by the hospital pharmacy pursuant to this subrule.

c. Advertising compounding services. ~~Compounding pharmacies or pharmacists~~ A compounding pharmacy or pharmacist may advertise or otherwise promote the fact that ~~they provide~~ the pharmacy or pharmacist provides prescription drug compounding services. ~~Compounding pharmacies or pharmacists~~ A compounding pharmacy or pharmacist shall not make a claim, assertion, or inference of professional superiority in the compounding of drug products that cannot be substantiated. All advertisements shall meet the requirements contained in rule 657—8.12(126,147).

d. *Central fill or processing of compounded drug products.* Nothing in these rules shall prohibit the centralized filling or processing of a prescription drug order for a compounded drug product by a central fill or processing pharmacy on behalf of an originating pharmacy as provided in 657—Chapter 18.

e. *Compounding for research.* A compounding pharmacy may compound drug products and placebos for dispensing to subjects involved in an approved blinded university or college research project. Drug products and placebos compounded for this purpose shall be labeled as provided in the research protocol and may be dispensed directly to patients, delivered to another pharmacy for delivery to patients, or delivered to the researcher for delivery to patients. Provisions of subrule 20.3(1) prohibiting the compounding of commercially available products shall not apply to the compounding of products and placebos for research pursuant to this paragraph.

20.3(5) No change.

ITEM 13. Amend subrule 20.6(2) as follows:

20.6(2) *Radiopharmaceuticals.* If radiopharmaceuticals are being compounded, the requirements of 657—Chapter 16 and rule 657—13.20(124,155A) shall be met.

ITEM 14. Amend subrule 20.10(3) as follows:

20.10(3) *Record.* A production record shall be prepared and kept for each drug product compounded for an individual patient. A production record is not required when a drug is mixed or reconstituted according to the product's labeling or the manufacturer's directions. The record shall include the following information:

a. Production date;

b. List of ingredients and quantity of each ingredient used;

c. Initials or unique identification of each person involved in each of the compounding steps;

d. Initials or unique identification of each pharmacist verifying each of the compounding steps;

e. Internal control or prescription number and, if the prescription is filled using a product compounded in bulk pursuant to rule 657—20.11(126), the internal control number assigned to the batch and recorded in the batch production record.

ITEM 15. Amend subrule 20.10(8) as follows:

20.10(8) *Labeling and control of excess products.* When a quantity of a compounded drug product is prepared in excess of that to be initially dispensed, the excess product shall be labeled, stored, and accounted for pursuant to rule 657—20.11(126).

ITEM 16. Amend rule 657—20.11(126) as follows:

657—20.11(126) Bulk compounding.

20.11(1) No change.

20.11(2) *Production record.* For each batch of drug product compounded, a production record containing the following information shall be prepared and maintained:

a. The information from the master formula record;

b. Records of each step in the compounding process including:

(1) Preparation date;

(2) Identification of ingredients (including lot numbers);

(3) Quantities of ingredients used;

(4) Initials or unique identification of person completing each step;

(5) Initials or unique identification of pharmacist verifying each step;

c. Expiration/beyond-use date;

d. Internal control number;

e. Total yield.

20.11(3) No change.